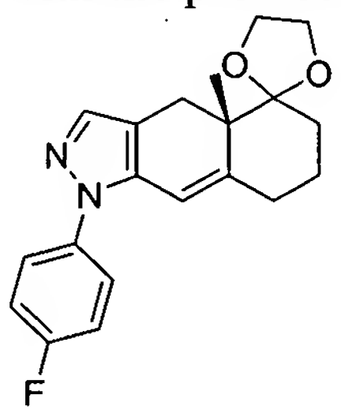
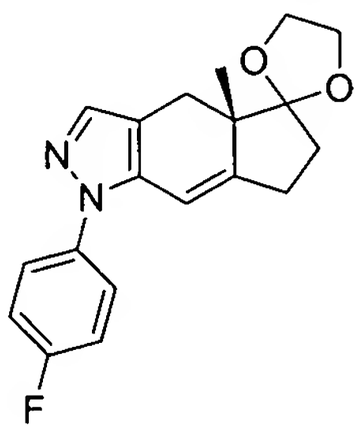
REMARKS

Status of Claims

Claims 8-14 and 22 are pending in the application prior to the instant amendments. Claim 8 is currently amended, no claim is added or canceled, leaving claims 8-14 and 22 pending upon entry of the instant amendment.

Indication of allowability - Applicants acknowledge the examiner's indication of allowability of claims 11-13.

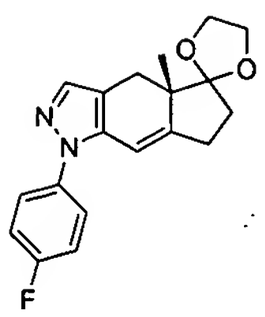
Amendment to claim 8 - Claim 8 is amended, as indicated in the listing of claims herein, to read as the following:

> Claim 8. A pharmaceutical composition comprising a compound of Formula I
>
> ...
>
> with the proviso that the compound of Formula I is other than
>
> 
>
> and  .

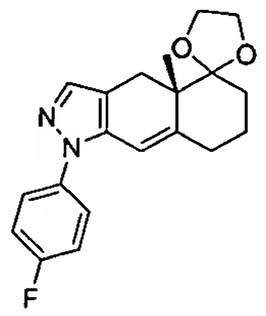
Support for this amendment is found at least at the bottom of page 87 of the application (Example 142). No new matter has been added. Accordingly, entry thereof is respectfully requested.

Phone Interview Summary

On September 16, 2008, a phone interview was conducted between Examiner Sun Jae Y. Loewe and Applicants' attorney Yong Zhao. The patentability of claim 8 was discussed during the interview. The Examiner maintained the 35 U.S.C. §102(e) rejection citing the reference WO 04/075840 (Ali et al.) as disclosing the following compound:

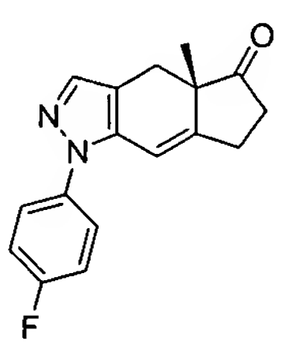


The Examiner further elaborated that WO 04/075840 discloses the above compound as this reference provides that Compound A can be prepared following the same reaction procedure described for the preparation of Compound B and the procedure for



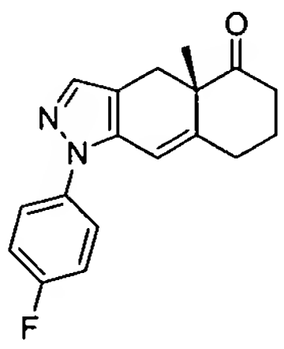
Compound B discloses the compound . Specifically, WO 04/075840 provides:

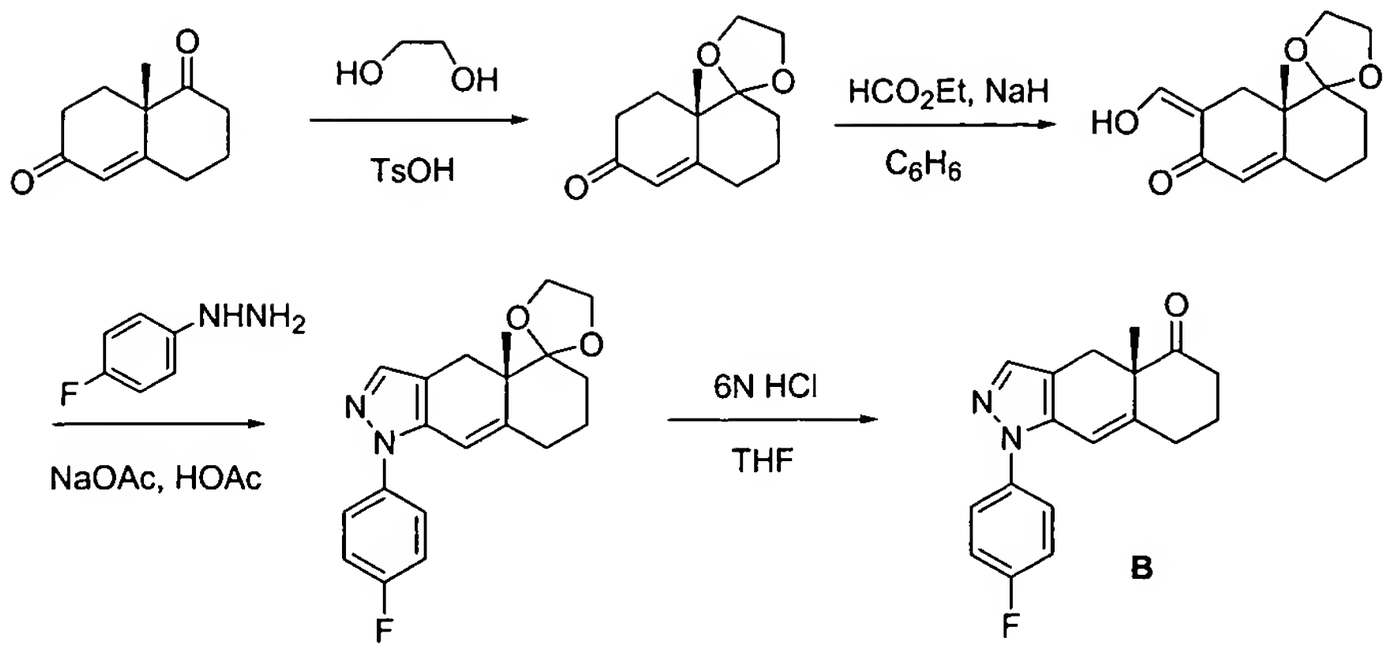
COMPOUND A



COMPOUND A was prepared from the known Hajos-Parrish ketone (J. Org. Chenz. 1974, 39(12), 1612-1621.) following the same reaction sequence and procedure described below for the preparation of COMPOUND B.

COMPOUND B

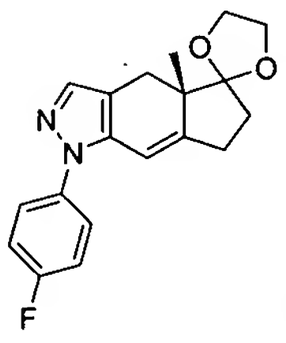




...

(WO 04/075840, line 1, p. 35 – line 5, p. 36)

Applicants disagreed with the Examiner regarding the teaching of the compound

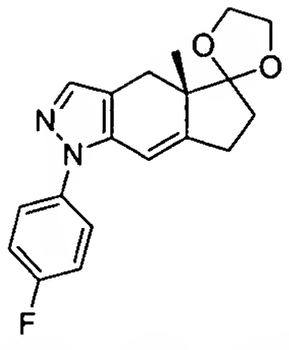


by the cited reference, but agreed to respond to the rejections in the next amendment.

Rejections under 35 U.S.C. §102 (e)

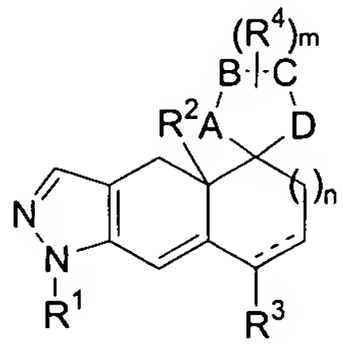
At page 2 of the Final Office Action dated May 1, 2008, the Examiner rejects claims 8-10, 14 and 22 under 35 U.S.C. §102(e). In particular, the Examiner alleges:

> 4. Claims 8-10, 14 and 22 rejected under 35 U.S.C. 102(e) as being anticipated by the following three references: a) Ali et al. (WO 04/075840; step 3 on p. 37), scheme 3 on p. 32, disclosure on p. 35-36; b) Ali et al. (WO 04/026248, step c on p. 39); c) Ali et al. (WO 2003/086294, step 3 on p. 43).
> ...
>
> The three references teach the compound shown below in a composition comprising 40 mL of acetic acid in 1 L of water (ie. Aqueous solution).

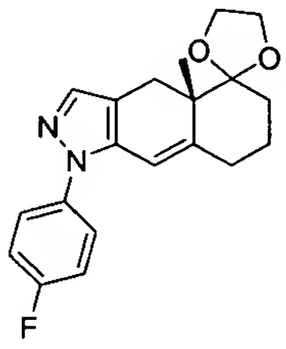


(Office Action dated May 01, 2008, pages 2-3) Applicants respectfully traverse this rejection.

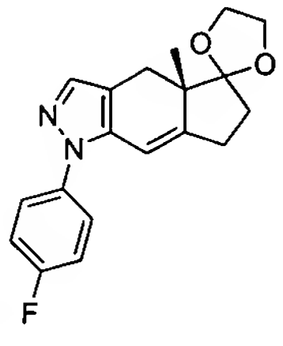
Claims 8-10 - Applicants point out that all three cited references are directed to selective glucocorticoid receptor modulators having vastly different chemical structures than the instantly claimed compounds. Specifically, the instantly claimed compounds have the following general structure wherein the -A-B-C-D- ring is a spirocyclic ring connected to the three-ring core structure:

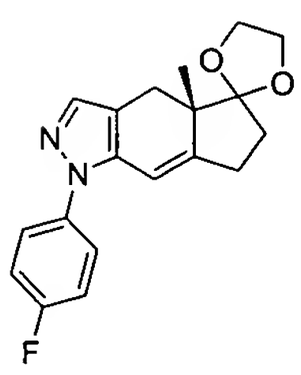


On the other hand, the only spirocyclic compound at the –A-B-C-D- position disclosed by the cited references has the following structure and is disclosed as a reaction intermediate, not as an active compound:

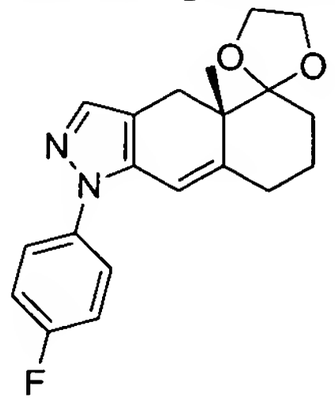
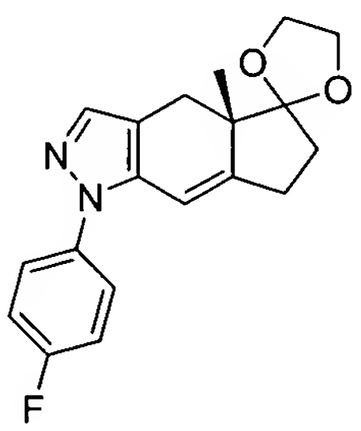


(WO 04/075840, reaction scheme on p. 36); WO 04/026248, step b on p. 39; and WO 03/086294, reaction scheme on p. 42)

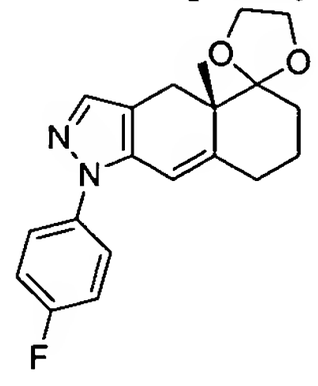
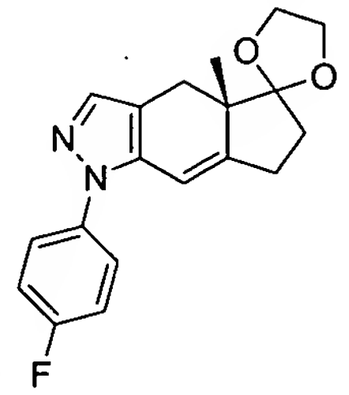
Moreover, contrary to the position of the Examiner, none of the cited references explicitly discloses the compound of  .

Furthermore, even assuming that WO 04/075840 had taught the compound of  , this compound would have been disclosed as a reaction intermediate, not as an active compound.

Notwithstanding the above argument, to advance the prosecution of the instant application, Applicants have amended claim 8 to read as the following:

> Claim 8. A pharmaceutical composition comprising a compound of Formula I …
> with the proviso that the compound of Formula I is other than
> 
> and  .

Applicants point out that none of the cited references disclose all limitations of claim 8 as amended. Therefore, claim 8 and its dependent claims 9-10 are novel over the cited references. Applicants respectfully request withdraw of the §102(e) rejection and allowance of claims 8-10 in view of the current amendment.

Claim 14 – Claim 14 is directed to a particular spirocyclic compound as specified in the Listing of Claims section. Additionally, neither  nor  is in Claim 14. Thus, claim 14 is novel over the cited references as none of the references disclose all limitations of this claim. Applicants respectfully request withdraw of the §102(e) rejection and allowance of claim 14.

Claim 22 – Claim 22 depends from allowable claim 11 and further requires that the pharmaceutical composition comprise a pharmaceutically acceptable carrier. Since claim 11 is novel and has been allowed, its dependent claim 22 also is novel over the cited references. Accordingly, Applicants respectfully request withdraw of the §102(e) rejection and allowance of claim 22.

In view of the foregoing amendment and remarks, Applicants submit that the application is now in condition for allowance and passage thereto is earnestly requested. Any additional fees required in connection with this Amendment may be taken from Merck Deposit Account No. 13-2755. The Examiner is invited to contact the undersigned attorney at the telephone number provided below to advance the prosecution of the case.

Respectfully submitted,

By _____

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Date: October 1, 2008